Author Index for Volume 21

Altman, DG, 184S, 488
Anderson, RT, 171S
Andriole, GL, 273S

Babiker, AG, 75
Bain, RP, 428
Barrow, S, 356S
Bautista, OM, 428
Beck, GJ, 502
Begg, CB, 241
Belseck, E, 476
Bennet, N, 62
Bhat, N, 349S
Bjerg, AM, 223
Bonk, J, 356S
Borst, C, 595
Bouchet, C, 30
Bowen, DJ, 195S, 206S, 226S
Brandt, CA, 440
Brawley, LR, 156S, 164S
Bredée, JJ, 595
Bresalier, RS, 273S
Briançon, S, 30
Broski, KG, 356S
Browne, JEH, 310S
Brustia, L, 103
Bugnard, F, 383
Buskens, E, 595
Buys, SS, 273S
Buyse, M, 415

Caporaso, N, 349S
Carroll, RJ, 343
Caughman, C, 329S
Chao, D, 212S
Chappell, R, 138
Chatellier, G, 383
Chen, YQ, 369
Chia, D, 273S
Childs, J, 356S
Cohen, S, 171S
Collins, K, 244
Colton, T, 415
Cook, TD, 208
Crawford, ED, 273S
Crowley, JJ, 343
Culos-Reed, SN, 156S, 200S

Darbyshire, JH, 75
Dawson, C, 462
Day, S, 330
De Amici, D, 103
de Jaegere, PPT, 595
de Klerk, E, 540
de Medina, EOR, 595
DeMets, DL, 54, 190, 313
Diephuis, JC, 595
Dixon, DO, 1
Dorgan, M, 476
Dugan, E, 226S
Dumas, JE, 286
Dunbar-Jacob, J, 195S
DYABHYCAR Study group, 383

Edler, L, 415
Eefting, FD, 595
Eknoyan, G, 502
Ellenberg, SS, 498
Ellis, S, 218S
Engelhard, D, 356S
ERA Investigators, 257
Evans, S, 415

Fagerstrom, RM, 329S, 390S
Farmer, D, 212S
Fazzari, M, 360
Fijal, BA, 7
Fink, J, 62
Fisk, JM, 440
Flickinger, LM, 329S, 356S
Fogel, R, 273S
Ford, ME, 379S
Fouad, M, 356S, 379S
Foy, CG, 212S

Gahagan, B, 356S
Gamito, E, 356S
Gassman, JJ, 502
Geisinger, KR, 257
Geller, NL, 415
Gelmann, EP, 273S
George, SL, 415
Ghosh, D, 115
Gilbert, F, 273S
Gilpin, AK, 462
Glenny, AM, 488
Gluud, C, 223
Gohagan, JK, 249S, 251S, 273S, 310S, 349S
Gong, J, 313
Gotch, FA, 502
Gottschau, A, 223
Greene, T, 502
Gren, LH, 356S
Grobbee, DE, 595
Guillemin, F, 30

Hall, JM, 7
Hamilton, G, 62
Hamilton, SA, 44
Haralson, JC, 329S
Harrell, FE Jr, 305
Hartge, P, 349S
Hasson, MA, 273S, 329S
Hayes, RB, 251S, 273S, 349S
Heller, G, 360
HEMO Study Group, 502
Herrington, DM, 257
Hilke, C, 356S
Homik, J, 476
Hoover, RN, 349S
Hsieh, FY, 552
Hutton, JL, 415

Ibrahim, JG, 574
Iglewicz, B, 127
INFO Trial Group, The, 223
ISCB Subcommittee on Fraud, 415

Jamrozik, K, 244
Jansen, EWL, 595
Jernigan, JC, 379S
Johnson, BF, 62
Johnson, CC, 273S, 349S, 356S

Kahane, DC, 329S
Kaplan, RM, 233S
Karras, BT, 440
Kealey, KA, 144
Kidd, KE, 184S

Controlled Clinical Trials 21:610–611 (2000)

© Elsevier Science Inc. 2000

655 Avenue of the Americas, New York, NY 10010

0197-2456/00/$–see front matter

King, DW, 94
Kjaergard, LL, 223
Klein, KP, 257
Klersy, C, 103
Knape, JTA, 595
Kopp, W, 349S
Kramer, BS, 251S
Krogsgaard, K, 223
Kruse, AY, 223
Kusek, JW, 502
KyungMann, K, 190

Lachenbruch, P, 415
Lachin, JM, 167, 428
Lagakos, SW, 1
Lamerato, L, 356S
Lan, KKG, 190
Lappe, K, 356S
Lashley, R, 94
Laughlin, JE, 286
Lavori, PW, 552
Legedza, ATR, 574
Lesaffre, E, 415, 540
Levey, AS, 502
Levin, DL, 310S
Levin, NW, 502
Lew, R, 62
Lièvre, M, 383
Lu, C, 440
Lu, J, 561
Lucey, G, 62

Mandel, JS, 273S
Mann, SL, 144
Marek, PM, 144
Marenco, L, 440
Marre, M, 383
Martin, J, 356S
Martin, KA, 195S
MASTER Trial Study Group, 244
McAuley, E, 164S, 200S
McBride, JS, 171S
McGuire, C, 356S
McMahon, RP, 305
Meinert, CL, 462
Mick, R, 343
Miller, AB, 400S
Miller, DS, 379S
Miller, PL, 440
Mortensen, EL, 223
Murray, G, 415
Myers, MH, 329S
Myles, PS, 244

Nadkarni, P, 440
Nathoe, HM, 595
Nichaman, L, 310S
Nierich, AP, 595

O'Brien, B, 273S, 310S, 390S
Oberman, A, 273S
Ockene, JK, 200S, 206S
Ogden, SL, 356S
Oken, MM, 273S
Ory, M, 171S

Pajak, TF, 561
Palace, C, 349S
Parsons, RW, 244
Paul-Dauphin, A, 30
Perri, MG, 195S, 206S
Peterson, AV Jr, 144
Peyton, P, 244
Pharmacological Intervention Working Group, 218S
Pinheiro, JC, 313
Plouin, PF, 383
Politi, P, 103
Prinz, RJ, 286
Prorok, PC, 251S, 273S, 310S
Proschan, MA, 527

Raab, GM, 330
Radial Artery Patency Study Investigators, 397
Rafla, S, 273S
Ramajoli, F, 103
Ramos-Remus, C, 476
Rand, CS, 188S, 218S, 241
Ranstam, J, 415
Rapp, SR, 164S, 188S
Reboussin, DM, 190, 257
Reding, D, 273S, 349S
Réglier, JC, 383
Rejeski, WJ, 155S, 164S, 200S
Ribisl, PM, 188S
Richardson, L, 383
Rigg, JRA, 244
Rosal, MC, 206S
Roter, DL, 200S
Rothman, N, 349S
Rutt, W, 273S

Sales, J, 330
Schacter, L, 440
Scher, HI, 360
Scherrer, B, 415
Schulman, G, 502
Schwemer, G, 21
Sevick, MA, 188S, 206S, 241S
Sharp, PC, 257
Sherman, AM, 206S
Shumaker, SA, 155S, 218S, 226S, 257
Sieber, WJ, 218S, 233S
Silbert, B, 244
Simpson, NK, 356S, 379S
Smith, EP, 286
Snyder, TE, 257
Song, F, 488
Stallings, FL, 379S
Suarez-Almazor, ME, 476
Subar, AF, 349S
Sullivan, D, 356S

Thompson, J, 356S
Trauth, JM, 379S
Trocky, N, 356S
Turner, LM, 329S

Ünalp, A, 462

van Dijk, D, 595
Vasmant, D, 383
Vitolins, MZ, 188S, 206S

Waclawiw, MA, 527
Walker, AS, 75
Walsh, JH, 329S
Wang, MC, 369
Weissfeld, JL, 273S, 349S, 390S, 400S
Wenzel, B, 329S
Wiens, BL, 127
Witte, JS, 7

Yokochi, L, 273S
Yurgalevitch, S, 400S

Ziegler, RG, 349S

ELSEVIER

Subject Index for Volume 21

ACCELERATED HAZARDS MODELS
Estimating the Treatment Effect with the Accelerated Hazards Models, 369

ADHERENCE
A Design for Testing Interventions to Improve Adherence Within a Hypertension Clinical Trial, 62
Adherence in Social Context, 184S
Adherence to Pharmacological Interventions: Current Trends and Future Directions, 218S
Dietary Adherence: Characteristics and Interventions, 206S
Enhancing Adherence in Randomized Controlled Clinical Trials, 226S
Estimating the Power of Compliance—Improving Methods, 540
Ethics in Adherence Promotion and Monitoring, 241S
Exercise Adherence among Older Adults: Challenges and Strategies, 212S
Informed Adherence: The Need for Shared Medical Decision Making, 233S
Issues of Aging and Adherence to Health Interventions, 171S
Measuring Adherence to Behavioral and Medical Interventions, 188S
Predictors of Adherence to Behavioral Change Interventions in the Elderly, 200S
Studying Adherence to Therapeutic Regimens: Overview, Theories, Recommendations, 156S
Who Will Adhere? Key Issues in the Study and Prediction of Adherence in Randomized Controlled Trials, 195S

AGING. *See also* ELDERLY
Issues of Aging and Adherence to Health Interventions, 171S

AIDS
Analysis of Multivariate Failure-time-Data from HIV Clinical Trials, 75
Clinical Trials in the Genomic Era: Effects of Protective Genotypes on Sample Size and Duration of Trial, 7

ANESTHESIA
Design of the Multicenter Australian Study of Epidural Anesthesia and Analgesia in Major Surgery: The MASTER Trial, 244
Impact of the Hawthorne Effect in a Longitudinal Clinical Study: The Case of Anesthesia, 103

ATHEROSCLEROSIS
Multicenter Radial Artery Patency Study (RAPS): Study design, 397
The Estrogen Replacement and Atherosclerosis (ERA) Study: Study Design and Baseline Characteristics of the Cohort, 257

AZT TREATMENT
Analysis of Multivariate Failure-time Data from HIV Clinical Trials, 75

BEHAVIOR CHANGE INTERVENTION
Adherence to Pharmacological Interventions: Current Trends and Future Directions, 218S
An Examination of Theory and Behavior Change in Randomized Clinical Trials, 164S
Dietary Adherence: Characteristics and Interventions, 206S
Exercise Adherence among Older Adults: Challenges and Strategies, 212S
Measuring Adherence to Behavioral and Medical Interventions, 188S
Predictors of Adherence to Behavioral Change Interventions in the Elderly, 200S
Studying Adherence to Therapeutic Regimens: Overview, Theories, Recommendations, 156S

Controlled Clinical Trials 21:612–622 (2000)
© Elsevier Science Inc. 2000
655 Avenue of the Americas, New York, NY 10010

0197-2456/00/$–see front matter

Who Will Adhere? Key Issues in the Study and Prediction of Adherence in Randomized Controlled Trials, 195S

BETA DISTRIBUTION
Estimating the Power of Compliance—Improving Methods, 540

BIAS. *See* GENDER BIAS

BIOSTATISTICS
Fraud in Medical Research: An International Survey of Biostatisticians, 415

BONFERRONI METHOD
Estimating Significance Level and Power Comparisons for Testing Multiple Endpoints in Clinical Trials, 313
Practical Guidelines for Multiplicity Adjustment in Clinical Trials, 527

BOOK REVIEWS
Applied Survival Analysis, 56
Basic Statistics and Pharmaceutical Statistical Applications, 593
Cardiovascular Drug Development: Protocol Design and Methodology, 140

CANCER SCREENING
Black Participation in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 379S
Coordination and Management of a Large Multicenter Screening Trial: The PLCO Cancer Screening Trial, 310S
Death Review Process in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 400S
Design and Evolution of the Data Management Systems in the PLCO Cancer Screening Trial, 329S
Design of the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 273S
Etiologic and Early Marker Studies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 349S
Informed Adherence: The Need for Shared Medical Decision Making, 233S
Quality Control of Cancer Screening Examination Procedures in the PLCO Cancer Screening Trial, 390S
Recruitment Strategies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial: The First 6 Years, 356S
The PLCO Cancer Screening Trial of the National Cancer Institute: History, Organization, and Status, 251S
The Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 249S

CANCER TREATMENTS
Phase II Clinical Trial Design for Noncytotoxic Anticancer Agents for Which Time to Disease Progression is the Primary Endpoint, 343
The Phase II/III Transition: Toward the Proof of Efficacy in Cancer Clinical Trials, 360

CARDIOVASCULAR DISEASE
Adjusting Survival Analysis for the Presence of Unadjudicated Study Events, 208
Practical Guidelines for Multiplicity Adjustment in Clinical Trials, 527
The Estrogen Replacement and Atherosclerosis (ERA) Study: Study Design and Baseline Characteristics of the Cohort, 257
The Non-Insulin-Dependent Diabetes, Hypertension, Microalbuminuria or Proteinuria, Cardiovascular Events, and Ramipril (DIABHYCAR) Study: Design, Organization, and Patient Recruitment, 383
The Octopus Study: Rationale and Design of Two Randomized Trials on Medical Effectiveness, Safety, and Cost Effectiveness of Bypass Surgery on the Beating Heart, 595

CHILDHOOD CONDUCT DISORDERS
The EARLY ALLIANCE Prevention Trial: A Dual Design to Test Reduction of Risk for Conduct

Problems, Substance Abuse, and School Failure in Childhood, 286

COLORECTAL CANCER
Black Participation in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 379S
Coordination and Management of a Large Multicenter Screening Trial: The PLCO Cancer Screening Trial, 310S
Death Review Process in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 400S
Design and Evolution of the Data Management Systems in the PLCO Cancer Screening Trial, 329S
Design of the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 273S
Etiologic and Early Marker Studies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 349S
Identifying Clinical Trials in the Medical Literature with Electronic Databases: MEDLINE Alone is Not Enough, 476
Indirect Comparison in Evaluating Relative Efficacy Illustrated by Antimicrobial Prophylaxis in Colorectal Surgery, 488
Quality Control of Cancer Screening Examination Procedures in the PLCO Cancer Screening Trial, 390S
Recruitment Strategies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial: The First 6 Years, 356S
Reengineering a Database for Clinical Trials Management: Lessons for System Architects, 440
The PLCO Cancer Screening Trial of the National Cancer Institute: History, Organization, and Status, 251S
The Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 249S

COMPLIANCE. *See* ADHERENCE

CONDITIONAL POWER
A Flexible Stochastic Curtailing Procedure for the Log-Rank Test, 428

CONTINUAL REASSESSMENT METHOD
Longitudinal Design for Phase I Clinical Trials Using the Continual Reassessment Method, 574

CONTINUOUS SAMPLING PLANS
A Quantifiable Alternative to Double Data Entry, 94

CORONARY BYPASS SURGERY
Multicenter Radial Artery Patency Study (RAPS): Study design, 397
The Octopus Study: Rationale and Design of Two Randomized trials on Medical Effectiveness, Safety, and Cost Effectiveness of Bypass Surgery on the Beating Heart, 595

CORONARY HEART DISEASE. *See* CARDIOVASCULAR DISEASE

COVARIANCE ANALYSIS
How to Select Covariates to Include in the Analysis of a Clinical Trial, 330

COX REGRESSION MODELS
Design and Statistical Issues of the Hemodialysis (HEMO) Study, 502

CUMULATIVE INCIDENCE
Methods for Analysis of Multiple Events in the Presence of Death, 115

CYTOSTATIC AGENTS
Phase II Clinical Trial Design for Noncytotoxic Anticancer Agents for Which Time to Disease Progression is the Primary Endpoint, 343

DATA MANAGEMENT
Coordination and Management of a Large Multicenter Screening Trial: The PLCO Cancer Screening Trial, 310S
Design and Evolution of the Data Management Systems in the PLCO Cancer Screening Trial, 329S

DEATH
Death Review Process in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 400S
Methods for Analysis of Multiple Events in the Presence of Death, 115

DESIGN PAPERS
A Design for Testing Interventions to Improve Adherence Within a Hypertension Clinical Trial, 62
Design and Statistical Issues of the Hemodialysis (HEMO) Study, 502
Design of the Multicenter Australian Study of Epidural Anesthesia and Analgesia in Major Surgery: The MASTER Trial, 244
Design of the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 273S
Experimental Design and Methods for School-Based Randomized Trials: Experience from the Hutchinson Smoking Prevention Project (HSPP), 144
Multicenter Radial Artery Patency Study (RAPS): Study design, 397
The EARLY ALLIANCE Prevention Trial: A Dual Design to Test Reduction of Risk for Conduct Problems, Substance Abuse, and School Failure in Childhood, 286
The Estrogen Replacement and Atherosclerosis (ERA) Study: Study Design and Baseline Characteristics of the Cohort, 257
The Non-Insulin-Dependent Diabetes, Hypertension, Microalbuminuria or Proteinuria, Cardiovascular Events, and Ramipril (DIABHYCAR) Study: Design, Organization, and Patient Recruitment, 383
The Octopus Study: Rationale and Design of Two Randomized trials on Medical Effectiveness, Safety, and Cost Effectiveness of Bypass Surgery on the Beating Heart, 595

DIABETES
The Non-Insulin-Dependent Diabetes, Hypertension, MIcroalbuminuria or Proteinuria, Cardiovascular Events, and Ramipril (DIABHYCAR) Study: Design, Organization, and Patient Recruitment, 383

DIALYSIS
Design and Statistical Issues of the Hemodialysis (HEMO) Study, 502

DIET
Dietary Adherence: Characteristics and Interventions, 206S
Measuring Adherence to Behavioral and Medical Interventions, 188S
Predictors of Adherence to Behavioral Change Interventions in the Elderly, 200S
Who Will Adhere? Key Issues in the Study and Prediction of Adherence in Randomized Controlled Trials, 195S

DISEASE SUSCEPTIBILITY
Clinical Trials in the Genomic Era: Effects of Protective Genotypes on Sample Size and Duration of Trial, 7

DOUBLE DATA ENTRY
A Quantifiable Alternative to Double Data Entry, 94

DYNAMIC RANDOMIZATION
Dynamically Allocating Treatment When the Cost of Goods Is High and Drug Supply Is Limited, 44

EFFICACY ANALYSIS
Commentary: Ruminations on the Intent-to-Treat Principle, 241
Indirect Comparison in Evaluating Relative Efficacy Illustrated by Antimicrobial Prophylaxis in Colorectal Surgery, 488
Statistical Considerations in the Intent-to-Treat Principle, 167

ELDERLY
Adherence in Social Context, 184S
Adherence to Pharmacological Interventions: Current Trends and Future Directions, 218S
Exercise Adherence among Older Adults: Challenges and Strategies, 212S
Issues of Aging and Adherence to Health Interventions, 171S

Predictors of Adherence to Behavioral Change Interventions in the Elderly, 200S
Who Will Adhere? Key Issues in the Study and Prediction of Adherence in Randomized Controlled Trials, 195S

ELECTRONIC DATABASES
Gender Representation in Trials, 462
Identifying Clinical Trials in the Medical Literature with Electronic Databases: MEDLINE Alone is Not Enough, 476

EPIDURAL ANALGESIA
Design of the Multicenter Australian Study of Epidural Anesthesia and Analgesia in Major Surgery: The MASTER Trial, 244

EQUIVALENCE OF TREATMENTS
Design and Analysis of Three Treatment Equivalence Trials, 127

ESTROGEN REPLACEMENT THERAPY
The Estrogen Replacement and Atherosclerosis (ERA) Study: Study Design and Baseline Characteristics of the Cohort, 257

ETHICS
Ethics in Adherence Promotion and Monitoring, 241S

ETIOLOGY
Etiologic and Early Marker Studies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 349S

EVENT CLASSIFICATION
Adjusting Survival Analysis for the Presence of Unadjudicated Study Events, 208

EXERCISE. *See* PHYSICAL ACTIVITY

FAILURE TIMES
Phase II Clinical Trial Design for Noncytotoxic Anticancer Agents for Which Time to Disease Progression is the Primary Endpoint, 343

FAMILYWISE ERROR RATE
Practical Guidelines for Multiplicity Adjustment in Clinical Trials, 527

FRAUD. *See* SCIENTIFIC FRAUD

GENDER BIAS
Gender Representation in Trials, 462

GENERALIZABILITY
General Linear Models for Multicenter Clinical Trials, 21
Indirect Comparison in Evaluating Relative Efficacy Illustrated by Antimicrobial Prophylaxis in Colorectal Surgery, 488

GENETIC SCREENING
Clinical Trials in the Genomic Era: Effects of Protective Genotypes on Sample Size and Duration of Trial, 7
Etiologic and Early Marker Studies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 349S
The PLCO Cancer Screening Trial of the National Cancer Institute: History, Organization, and Status, 251S

GLOBAL TEST
Estimating Significance Level and Power Comparisons for Testing Multiple Endpoints in Clinical Trials, 313

GROUP SEQUENTIAL ANALYSIS
Statistical Power for a Long-Term Survival Trial with a Time-Dependent Treatment Effect, 561

HAWTHORNE EFFECT
Impact of the Hawthorne Effect in a Longitudinal Clinical Study: The Case of Anesthesia, 103

HEALTH INTERVENTION
Adherence in Social Context, 184S
Issues of Aging and Adherence to Health Interventions, 171S
Measuring Adherence to Behavioral and Medical Interventions, 188S
Selection of Quality-of-Life Measures for a Prevention Trial: A Psychometric Analysis, 30

HIV INFECTION
Analysis of Multivariate Failure-time Data from HIV Clinical Trials, 75
Clinical Trials in the Genomic Era: Effects of Protective Genotypes on Sample Size and Duration of Trial, 7

HYPERTENSION
A Design for Testing Interventions to Improve Adherence Within a Hypertension Clinical Trial, 62

INDIRECT COMPARISONS
Indirect Comparison in Evaluating Relative Efficacy Illustrated by Antimicrobial Prophylaxis in Colorectal Surgery, 488

INFORMATION SHARING
Commentary: Relationships Between Data Monitoring Committees, 54

INFORMED CONSENT
Ethics in Adherence Promotion and Monitoring, 241S
Impact of the Hawthorne Effect in a Longitudinal Clinical Study: The Case of Anesthesia, 103

INTENT TO TREAT
Commentary: Ruminations on the Intent-to-Treat Principle, 241
Statistical Considerations in the Intent-to-Treat Principle, 167

INTERACTION
General Linear Models for Multicenter Clinical Trials, 21

INTERIM ANALYSIS
Adjusting Survival Analysis for the Presence of Unadjudicated Study Events, 208
Should Data and Safety Monitoring Boards Share Confidential Interim Data?, 1

INTERNET
Reengineering a Database for Clinical Trials Management: Lessons for System Architects, 440

INTERVENTION. *See* SCHOOL-BASED INTERVENTION

LOG-RANK TEST
A Flexible Stochastic Curtailing Procedure for the Log-Rank Test, 428
Statistical Power for a Long-Term Survival Trial with a Time-Dependent Treatment Effect, 561

LONGITUDINAL DESIGN
Longitudinal Design for Phase I Clinical Trials Using the Continual Reassessment Method, 574

LUNG CANCER
Black Participation in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 379S
Coordination and Management of a Large Multicenter Screening Trial: The PLCO Cancer Screening Trial, 310S
Death Review Process in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 400S
Design and Evolution of the Data Management Systems in the PLCO Cancer Screening Trial, 329S
Design of the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 273S
Etiologic and Early Marker Studies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 349S
Quality Control of Cancer Screening Examination Procedures in the PLCO Cancer Screening Trial, 390S
Recruitment Strategies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial: The First 6 Years, 356S
The PLCO Cancer Screening Trial of the National Cancer Institute: History, Organization, and Status, 251S
The Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 249S

MALIGNANT GLIOMAS
Estimating the Treatment Effect with the Accelerated Hazards Models, 369

MARGINAL MODELS
Analysis of Multivariate Failure-time Data from HIV Clinical Trials, 75

MEDLINE
Gender Representation in Trials, 462
Identifying Clinical Trials in the Medical Literature with Electronic Databases: MEDLINE Alone is Not Enough, 476

MINORITY GROUPS
Black Participation in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 379S

MISSING DATA
Power Calculation for Clinical Trials When the Outcome Is a Composite Ranking of Survival and a Nonfatal Outcome, 305
The Estrogen Replacement and Atherosclerosis (ERA) Study: Study Design and Baseline Characteristics of the Cohort, 257

MIXTURE MODEL
Estimating the Power of Compliance—Improving Methods, 540

MONITORING
A Quantifiable Alternative to Double Data Entry, 94
Commentary: Relationships between Data Monitoring Committees, 54
Should Data and Safety Monitoring Boards Share Confidential Interim Data?, 1

MULTICENTER TRIALS
Coordination and Management of a Large Multicenter Screening Trial: The PLCO Cancer Screening Trial, 310S
Gender Representation in Trials, 462
General Linear Models for Multicenter Clinical Trials, 21

MULTIPLE COMPARISONS
Design and Analysis of Three Treatment Equivalence Trials, 127
Practical Guidelines for Multiplicity Adjustment in Clinical Trials, 527

MULTIPLE EVENTS
Methods for Analysis of Multiple Events in the Presence of Death, 115

MULTIPLE OUTCOMES
Estimating Significance Level and Power Comparisons for Testing Multiple Endpoints in Clinical Trials, 313
Power Calculation for Clinical Trials When the Outcome Is a Composite Ranking of Survival and a Nonfatal Outcome, 305

MULTIVARIATE FAILURE-TIME DATA
Analysis of Multivariate Failure-time Data from HIV Clinical Trials, 75

NEUROPSYCHOLOGICAL TESTS
The Octopus Study: Rationale and Design of Two Randomized trials on Medical Effectiveness, Safety, and Cost Effectiveness of Bypass Surgery on the Beating Heart, 595

NONBINARY COVARIATES
Sample-Size Calculations for the Cox Proportional Hazards Regression Model with Nonbinary Covariates, 552

NUTRITION. *See* DIET

OLDER ADULTS. *See* ELDERLY

ORAL POTASSIUM
A Design for Testing Interventions to Improve Adherence Within a Hypertension Clinical Trial, 62

OUTCOMES MODEL
Informed Adherence: The Need for Shared Medical Decision Making, 233S

OVARIAN CANCER
Black Participation in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 379S
Coordination and Management of a Large Multicenter Screening Trial: The PLCO Cancer Screening Trial, 310S

Death Review Process in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 400S
Design and Evolution of the Data Management Systems in the PLCO Cancer Screening Trial, 329
Design of the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 273S
Etiologic and Early Marker Studies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 349S
Quality Control of Cancer Screening Examination Procedures in the PLCO Cancer Screening Trial, 390S
Recruitment Strategies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial: The First 6 Years, 356S
The PLCO Cancer Screening Trial of the National Cancer Institute: History, Organization, and Status, 251S
The Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 249S

PATIENT INFORMATION
A Randomized Trial Assessing the Impact of Written Information on Outpatients' Knowledge About and Attitude Toward Randomized Clinical Trials, 223

PATIENT RECORD SYSTEMS
Reengineering a Database for Clinical Trials Management: Lessons for System Architects, 440

PATIENT RECRUITMENT AND SELECTION
Black Participation in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 379S
Recruitment Strategies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial: The First 6 Years, 356S
The Non-Insulin-Dependent Diabetes, Hypertension, MIcroalbuminuria or Proteinuria, Cardiovascular Events, and Ramipril (DIABHYCAR) Study: Design, Organization, and Patient Recruitment, 383

PHARMACOLOGY
Adherence to Pharmacological Interventions: Current Trends and Future Directions, 218S
Measuring Adherence to Behavioral and Medical Interventions, 188S
Who Will Adhere? Key Issues in the Study and Prediction of Adherence in Randomized Controlled Trials, 195S

PHASE I TRIALS
Longitudinal Design for Phase I Clinical Trials Using the Continual Reassessment Method, 574

PHASE II TRIALS
Phase II Clinical Trial Design for Noncytotoxic Anticancer Agents for Which Time to Disease Progression is the Primary Endpoint, 343
The Phase II/III Transition: Toward the Proof of Efficacy in Cancer Clinical Trials, 360

PHYSICAL ACTIVITY
Exercise Adherence among Older Adults: Challenges and Strategies, 212S
Who Will Adhere? Key Issues in the Study and Prediction of Adherence in Randomized Controlled Trials, 195S

POOLING
General Linear Models for Multicenter Clinical Trials, 21

PREVENTION TRIALS
Enhancing Adherence in Randomized Controlled Clinical Trials, 226S
Experimental Design and Methods for School-Based Randomized Trials: Experience from the Hutchinson Smoking Prevention project (HSPP), 144
The EARLY ALLIANCE Prevention Trial: A Dual Design to Test Reduction of Risk for Conduct Problems, Substance Abuse, and School Failure in Childhood, 286

PROPORTIONAL HAZARDS REGRESSION
Sample-Size Calculations for the Cox Proportional Hazards Regression Model with Nonbinary Covariates, 552

PROSTATE CANCER
Black Participation in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 379S
Coordination and Management of a Large Multicenter Screening Trial: The PLCO Cancer Screening Trial, 310S
Death Review Process in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 400S
Design and Evolution of the Data Management Systems in the PLCO Cancer Screening Trial, 329S
Design of the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 273S
Etiologic and Early Marker Studies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 349S
Quality Control of Cancer Screening Examination Procedures in the PLCO Cancer Screening Trial, 390S
Recruitment Strategies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial: The First 6 Years, 356S
Statistical Power for a Long-Term Survival Trial with a Time-Dependent Treatment Effect, 561
The Phase II/III Transition: Toward the Proof of Efficacy in Cancer Clinical Trials, 360
The PLCO Cancer Screening Trial of the National Cancer Institute: History, Organization, and Status, 251S
The Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 249S

PROTECTIVE GENES
Clinical Trials in the Genomic Era: Effects of Protective Genotypes on Sample Size and Duration of Trial, 7

PSORIASIS
How to Select Covariates to Include in the Analysis of a Clinical Trial, 330

PSYCHOMETRIC PROPERTIES
Selection of Quality-of-Life Measures for a Prevention Trial: A Psychometric Analysis, 30

QUALITY ASSURANCE
A Quantifiable Alternative to Double Data Entry, 94
Coordination and Management of a Large Multicenter Screening Trial: The PLCO Cancer Screening Trial, 310S
Quality Control of Cancer Screening Examination Procedures in the PLCO Cancer Screening Trial, 390S

QUALITY OF LIFE
Selection of Quality-of-Life Measures for a Prevention Trial: A Psychometric Analysis, 30

QUESTIONNAIRES
A Randomized Trial Assessing the Impact of Written Information on Outpatients' Knowledge About and Attitude Toward Randomized Clinical Trials, 223
Commentary: Fraud Is Bad, Studying Fraud Is Hard, 498
Etiologic and Early Marker Studies in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial, 349S
Fraud in Medical Research: An International Survey of Biostatisticians, 415

RADIAL ARTERY
Multicenter Radial Artery Patency Study (RAPS): Study Design, 397

RAMIPRIL
The Non-Insulin-Dependent Diabetes, Hypertension, MIcroalbuminuria or Proteinuria, Cardiovascular Events, and Ramipril (DIABHYCAR) Study: Design, Organization, and Patient Recruitment, 383

RECURRENT EVENTS
Methods for Analysis of Multiple Events in the Presence of Death, 115

RENAL DISEASE
Design and Statistical Issues of the Hemodialysis (HEMO) Study, 502
Issues of Aging and Adherence to Health Interventions, 171S

REPEATED MEASURES
Computations for Group Sequential Boundaries Using the Lan-DeMets Spending Function Method, 190

RETENTION
Enhancing Adherence in Randomized Controlled Clinical Trials, 226S

RHEUMATIC DISEASES
Gender Representation in Trials, 476

SAMPLE SIZE
Clinical Trials in the Genomic Era: Effects of Protective Genotypes on Sample Size and Duration of Trial, 7
Sample-Size Calculations for the Cox Proportional Hazards Regression Model with Nonbinary Covariates, 552
The Phase II/III Transition: Toward the Proof of Efficacy in Cancer Clinical Trials, 360

SCHOLARSHIPS
Commentary: Student Scholarship Competition Manuscripts: Relevance, Rigor, and Promise, 138

SCHOOL-BASED INTERVENTION
Experimental Design and Methods for School-Based Randomized Trials: Experience from the Hutchinson Smoking Prevention project (HSPP), 144
The EARLY ALLIANCE Prevention Trial: A Dual Design to Test Reduction of Risk for Conduct Problems, Substance Abuse, and School Failure in Childhood, 286

SCIENTIFIC FRAUD
Commentary: Fraud Is Bad, Studying Fraud Is Hard, 498
Fraud in Medical Research: An International Survey of Biostatisticians, 415

SELECTION BIAS
Statistical Considerations in the Intent-to-Treat Principle, 167

SELF-EFFICACY THEORY
Studying Adherence to Therapeutic Regimens: Overview, Theories, Recommendations, 156S

SENSITIVITY ANALYSIS
Statistical Considerations in the Intent-to-Treat Principle, 167

SMOKING PREVENTION
Experimental Design and Methods for School-Based Randomized Trials: Experience from the Hutchinson Smoking Prevention project (HSPP), 144

SOCIAL-COGNITIVE THEORY
Studying Adherence to Therapeutic Regimens: Overview, Theories, Recommendations, 156S

SOFTWARE DESIGN
Design and Evolution of the Data Management Systems in the PLCO Cancer Screening Trial, 329S

SPENDING FUNCTION
Computations for Group Sequential Boundaries Using the Lan-DeMets Spending Function Method, 190

STATISTICAL POWER
Computations for Group Sequential Boundaries Using the Lan-DeMets Spending Function Method, 190
Statistical Power for a Long-Term Survival Trial with a Time-Dependent Treatment Effect, 561

STENT IMPLANTATION
The Octopus Study: Rationale and Design of Two Randomized trials on Medical Effectiveness, Safety, and Cost Effectiveness of Bypass Surgery on the Beating Heart, 595

STOCHASTIC CURTAILING
A Flexible Stochastic Curtailing Procedure for the Log-Rank Test, 428

STUDY DESIGN
Reengineering a Database for Clinical Trials Management: Lessons for System Architects, 440

SUBSTANCE ABUSE
The EARLY ALLIANCE Prevention Trial: A Dual Design to Test Reduction of Risk for Conduct Problems, Substance Abuse, and School Failure in Childhood, 286

SURROGATE ENDPOINTS
The Phase II/III Transition: Toward the Proof of Efficacy in Cancer Clinical Trials, 360

SURVIVAL ANALYSIS
A Flexible Stochastic Curtailing Procedure for the Log-Rank Test, 428
Adjusting Survival Analysis for the Presence of Unadjudicated Study Events, 208
Computations for Group Sequential Boundaries Using the Lan-DeMets Spending Function Method, 190

TERMINAL EVENT. *See* DEATH

THEORY DEVELOPMENT
An Examination of Theory and Behavior Change in Randomized Clinical Trials, 164S
Studying Adherence to Therapeutic Regimens: Overview, Theories, Recommendations, 156S

TIME-DEPENDENT TREATMENT EFFECT
Statistical Power for a Long-Term Survival Trial with a Time-Dependent Treatment Effect, 561

TOXICITY
Longitudinal Design for Phase I Clinical Trials Using the Continual Reassessment Method, 574

TREATMENT
Design and Analysis of Three Treatment Equivalence Trials, 127
Dynamically Allocating Treatment When the Cost of Goods Is High and Drug Supply Is Limited, 44

TYPE I ERROR
Computations for Group Sequential Boundaries Using the Lan-DeMets Spending Function Method, 190
Practical Guidelines for Multiplicity Adjustment in Clinical Trials, 527
Statistical Considerations in the Intent-to-Treat Principle, 167

UREA KINETIC MODELING
Design and Statistical Issues of the Hemodialysis (HEMO) Study, 502

VARIABLE SELECTION
How to Select Covariates to Include in the Analysis of a Clinical Trial, 330

VARIANCE INFLATION FACTOR
Sample-Size Calculations for the Cox Proportional Hazards Regression Model with Nonbinary Covariates, 552

VISUAL RECORD VERIFICATION
A Quantifiable Alternative to Double Data Entry, 94

WOMEN'S HEALTH
Gender Representation in Trials, 462
The Estrogen Replacement and Atherosclerosis (ERA) Study: Study Design and Baseline Characteristics of the Cohort, 257

WORST-RANK TEST
Power Calculation for Clinical Trials When the Outcome Is a Composite Ranking of Survival and a Nonfatal Outcome, 305